PATENT
Attorney Docket No.: 10123 - 03203 (01-535US03)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Wise et al.	
Serial No.: 09/864,488	Group Art Unit: 3767
Filed: May 24, 2001	Examiner: Phillip A. Gray
For: ANTI-CLOTTING METHODS AND APPARATUS FOR INDWELLING CATHETER TUBES	**Board of Patent Appeals and Interferences**

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on December 2, 2008 to the Appeal Brief filed on April 23, 2008, and pursuant to 37 C.F.R. § 41.41, Appellants present this Reply Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 56 and 59 - 81 in the Final Office Action dated October 9, 2007. The appealed claims are set forth in the attached Claims Appendix.

1. Status of the Claims

Claims 56, 59 - 66, 68 - 72, 74 - 79 and 80 - 81 have been rejected in the Final Office Action and are the subject of the present appeal. Claims 1 - 54 have been canceled. Claims 55, 57, 58, 67 and 73 have been withdrawn.

2. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Wijay (U.S. Pat. No. 5,158,540).

II. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Horzewski (U.S. Pat. No. 4,771,777).

III. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Cannon (U.S. Pat. No. 5,403,274).

IV. Whether claims 59 - 64 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Wijay or alternatively, under 35 U.S.C. § 103(a) as obvious over Wijay in view of Burns (U.S. Pat. No. 5,176,698).

V. Whether claims 70 - 72, 74 - 79 and 81 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wijay or alternatively, over Horzewski or alternatively, over Calderon or alternatively, over Cannon.

3. Argument

In the Examiner's Answer of 12/2/2008, the Examiner has withdrawn the 35 U.S.C. § 112, second paragraph, rejection of claim 56 as well as the 35 U.S.C. § 102(b) rejection of claims 56, 59-66, 68-69 and 80 over U.S. Patent No. 4,867,742 to Calderon.

I. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Wijay Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. 102(b) as anticipated by Wijay. (*See* 10/9/07 Office Action, pp. 2 - 6). In support of the rejection, the Examiner stated that Wijay discloses and is fully capable of being a system for establishing intermittent communication within the bloodstream. (*Id.*) The Examiner further adds that the elements taught by Wijay are fully capable of satisfying all structural, operational, functional and spatial limitations of the claims. (*Id.*; *See Also* 12/2/08 Examiner's Answer, pp. 4 - 5, 7)

B. Wijay does not Disclose a First Sealing Balloon Positionable Within a Distal End of the First Lumen to Seal the Distal End of the First Lumen as Recited in Claim 56

It is respectfully submitted that Wijay fails to teach or suggest a system for establishing intermittent fluid communication with a patient's bloodstream comprising "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 56.

In the Examiner's Answer, the Examiner has indicated that the balloon 16 of Wijay meets

the structural limitations of a first balloon positionable so that, when inflated, the balloon 16 seals a downstream end of the annular passage 30. (*See* 12/2/08 Examiner's Answer, p. 7). Initially, as noted in the Appeal Brief filed on April 23, 2008, the limitation of a first balloon positionable "*so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*," as recited in claim 56 is a structural limitation intended to specifically define physical characteristics (i.e., shape, size, location relative to features of the device, etc.) of a first balloon such that, when inflated, the distal end of the first lumen is sealed against flow by the first balloon.

The balloon 16 of Wijay does not meet the aforementioned limitation of claim 56. Specifically, the balloon 16 of Wijay is seated within an annular passage 30 spaced from a distal end thereof to close the *annular passage 30* for distal hemoperfusion. (*See* Wijay, col. 4, ll. 16 - 19; Fig. 1). However, it is noted that the balloon 16 is neither positioned nor positionable at "*a distal end*" of this annular passage and thus cannot prevent blood flow into the annular passage 30, as recited in claim 56. Rather, positioning of the balloon 16 is selected to allow blood and/or other fluids to enter into both proximal and distal portions of the annular passage while merely preventing a communication between the fluids in the respective proximal and distal portions -- i.e., preventing flow through the annular passage 30 past the balloon 16. Accordingly, when blood is pumped into the annular space 30, the balloon 16 prevents this blood from flowing out of the annular space 30 into the portion of the artery proximal to the balloon 17, redirecting the blood into the lumen 26 via holes 15 so that it may enter the artery distal to the balloon 17 and maintain blood flow through the artery. (*See* Wijay, col. 4, ll. 19 - 26). This function is in no way impacted by blood entering the distal end of the annular passage 30 and nothing in Wijay suggests that such operation of the balloon is desirable. It is therefore respectfully submitted that the balloon 16 is not designed to prevent blood from flowing into the distal portion of the annular

space 30, nor is the balloon 16 suitable for this purpose and that neither Wijay nor the Examiner provide any reason why such a position would be desirable or even acceptable in such a device.

It is therefore noted that Wijay does not teach or suggest "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*", as recited in claim 56.

Still further, it is respectfully submitted that employing a sealing balloon at a distal end of the annular space of the Wijay device to prevent blood flow thereinto, as recited in claim 56, would be detrimental to the functioning of the Wijay device. Specifically, Wijay is directed to maintaining fluid communication between the catheter and the lumen of the patient while merely changing the routes of this communication. (*See* Wijay, col. 2, ll. 55 - 59). Modifying the device of Wijay to prevent flow into the annular passage 30 at all when the balloon 16 is inflated would prevent blood flow into the openings 15 and therefore prove to be detrimental thereto. It is noted that if a proposed modification renders the purported invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (*See* In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). It is therefore respectfully submitted that the proposed modification of the Wijay device is an impermissible hindsight reconstruction of the invention and is insufficient to support a rejection under either of §102 and §103.

For these reasons, it is respectfully submitted that Wijay neither teaches nor suggests "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto,*" as recited in claim 56 and that claim 56 is allowable for at least this reason.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the

distal end of the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claims 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "sealing the first lumen to discontinue fluid communication with the bodily fluid by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and inflating the first balloon to seal the first lumen at the distal end thereof." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

II. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Horzewski Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. 102(b) as anticipated by Horzewski. (*See* 10/9/07 Office Action, p. 6). In support of the rejection, the Examiner has analogized the "first lumen" of claim 56 to the lumen 18 of

Horzewski, the "second lumen" to the multiple lumens extending through the tubular member 77 and the "first balloon" to the balloon 82. (*See* 12/2/08 Examiner's Answer, p. 8).

B. The Cited Reference does not Disclose a First Sealing Balloon Positionable Within a Distal End of the First Lumen, as Recited in Claim 56

Horzewski purports to show a perfusion-type dilation apparatus for regulating the flow of blood pumped into a stenosis. It is noted that Horzewski does not teach or suggest "a catheter including *first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto" and "a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 56.

Initially, it is respectfully submitted that Horzewski teaches *only one lumen* extending from a proximal end of the guiding catheter 12 to a distal end thereof, with the balloon 82 situated adjacent a distal portion of the guiding catheter 12. (*See* Horzewski, col. 2, ll. 28 - 30). Claim 56, on the other hand, recites the employment of "a catheter including *first and second* lumens extending therethrough." It is submitted that the tubular membrane 77 does not share proximal and distal ends with the tubular member guiding catheter 12 and therefore does not meet the aforementioned limitation of claim 56. (*See* Horzewski, Fig. 9). It is therefore submitted that Horzewski does not teach or suggest "*a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood

vessel of a patient," as recited in claim 56.

It is further submitted that Horzewski also fails to teach or suggest "a first sealing balloon positionable within a distal end of the first lumen, *so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto* ," as recited in claim 56 and that Horzewski actually teaches away from such an embodiment. Specifically, Horzewski teaches a balloon 82 situated along the tubular membrane 77 which contains a plurality of openings 92 and circumferentially placed holes 93. (*See* Horzewski, col. 5, line 65 to col. 6, line 12; Fig. 9). The openings 92 are designed to allow blood to travel to/from the stenosis even during inflation of the balloon 82 in order to avoid a situation where blood flow is temporarily blocked between the catheter and the stenosis. Specifically, Horzewski notes that "[b]lood therefore flows through the dilatation catheter into a region beyond the stenosis so that there is a continued supply of blood to the heart muscle during the period of inflation of the balloon." (*Horzewski*, col. 7, ll. 22 - 28). In the Examiner's Answer, the Examiner cited a recitation from Horzewski stating that "the first balloon 82 [...] prevents the flow of blood in the flow passage beyond that point." (*See* 12/2/08 Examiner's Answer, p. 8; *See Also* Horzewski; col. 7, ll. 19 - 25). However, it is submitted that this quotation has been taken out of context as Horzewski subsequently goes on to recite that "[the] blood then must pass through at least one opening 92 into the second lumen 91 and then through the openings 93 distal of the second balloon." (*Id.*). Accordingly, it is submitted that Horzewski clearly explains that the balloon 82 merely redirects the flow from the lumen 18 to the lumen 91 and does not teach any embodiment where a balloon seals the distal end of a first lumen "to prevent blood flow thereinto," as recited in claim 56. Rather, Horzewski deliberately tries to overcome a situation where blood flow would be blocked by introducing the plurality of openings 92 and circumferentially placed holes 93 into the design. It is therefore further noted that the employment of a design that "seals a distal end of the first lumen to prevent blood flow

thereinto," as recited in claim 56, would be detrimental to the operation of the Horzewski device which must permit constant fluid communication between the catheter and the stenosis of the artery. (*Id.*)

Thus, it is respectfully submitted that Horzewski neither teaches nor suggests "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, *the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for deflating the first balloon *to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel," as recited in claim 56 and that claim 56 is allowable.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claims 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to

blood flow thereinto while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "sealing the first lumen to discontinue fluid communication with the bodily fluid by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and inflating the first balloon to seal the first lumen at the distal end thereof" and "reestablishing fluid communication with the bodily fluid by deflating the first balloon to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

III. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Cannon Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. § 102(b) as anticipated by Cannon. (*See* Final Office Action, 10/9/07, p. 7).

B. The Cited Reference does not Disclose a First Sealing Balloon as Recited in Claim 56

Cannon does not teach or suggest "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, *the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*," as recited in claim 56. Specifically, Cannon purports to describe a guide catheter 12 for pressure equalization of fluids traveling between the guide catheter 12 and a

blood vessel, the guide catheter 12 comprising a balloon 44 located distally of a port 32 and at least one opening 48. (*See* Cannon, col. 2, line 64 – col. 3, line 11). The at least one opening 48 of Cannon permits fluid communication between the guide lumen 18, which the Examiner has analogized to the "first lumen" of claim 56, and the blood vessel BB. (*See* Cannon, col. 5, ll. 11 - 14). In light of the above, it is noted that the balloon 44 of Cannon is incapable of "seal[ing] the distal end of the first lumen to prevent blood flow thereinto," as recited in claim 56. Specifically, even after inflation of the balloon 44 within the guide catheter 12, fluid blood flow into the lumen 18 is permitted. The Examiner contends that "the inflation of the trapper balloon 44 effectively seals the distal end of the guide catheter 12." (*See* 12/2/08 Office Action, p. 8). However, it is respectfully submitted the that balloon 44 still fails to meet the limitation of "seal[ing] the distal end of the first lumen *to prevent blood flow thereinto*," as recited in claim 56 since blood flow is permissible into the lumen 18 via at least one of the port 32 and the opening(s) 48. It is therefore submitted that, not only does Cannon show no sealing of the lumen 18 such that blood flow thereinto is prevented, Cannon further teaches away from such a modification as a sealed end would prevent the performance of its intended function -- i.e., applying pressure to the plunger 62 to force fluid into the guide lumen 18 to initiate flow from the blood vessel and into the opening 48, from where the blood follows a predetermined path to the distal end 24 of the balloon catheter 20. (*See* Cannon, col. 6, ll. 3 - 10).

It is therefore respectfully submitted therefore that Cannon does not teach or suggest "a first sealing balloon positionable within a distal end of the first lumen, so that, *when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the first balloon to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel," as recited in claim 56 and that claim 56 is allowable.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claims 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter *to prevent blood in the vessel from entering the hollow interior passageway*" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen *to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the balloon to reopen the lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "*sealing the first lumen to discontinue fluid communication with the bodily fluid* by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and *inflating the first balloon to seal the first lumen at the distal end thereof*" and "*reestablishing fluid communication with the bodily fluid by deflating the first balloon* to initiate

a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

IV. The Rejection of Claims 59 - 64 as Anticipated by Wijay or, alternatively, as Obvious over Wijay in View of Burns Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 59 - 64 under 35 U.S.C. § 102(b) as anticipated by Wijay or alternatively, under 35 U.S.C. § 103(a) as obvious over Wijay in view of Burns. (*See* Final Office Action, 10/9/07, pp. 7 - 8).

B. The Cited Reference does not Disclose a First Sealing Balloon as Recited in Claim 56

As stated above, Wijay neither discloses nor suggests "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen," as recited in claim 59. It is respectfully submitted that Burns does not cure the deficiencies of Wijay. Specifically, the balloon 16 of Burns is disposed circumferentially around a distal end opening 47 of a shaft 14 and never seals or opens the distal end opening 47. Thus, it is respectfully submitted that Wijay and Burns taken either alone or in combination, neither show nor suggest inflating a "first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen," as recited in claim 59. Because claims 60 - 63 depend from, and, therefore include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of 59 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in

the vessel from entering the hollow interior passageway." Therefore, at least for the reasons described above with respect to claim 59, it is respectfully submitted that claim 64 is also allowable.

V. The Rejections of Claims 70 - 72, 74 - 79 and 81 as Obvious Over Wijay or Alternatively, Over Horzewski or, Alternatively, Over Cannon Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, and, as clarified in the Examiner's Answer, the Examiner rejected claims 70 - 72, 74 - 79 and 81 under 35 U.S.C. § 103(a) as obvious over Wijay or alternatively, over Horzewski or alternatively, over Cannon. (*See* 10/9/07 Office Action, p. 8; *See Also* 12/2/08 Examiner's Answer, p. 8).

B. The Cited References do not Teach or Suggest First and Second Balloons Positionable Within Distal Ends of First and Second Catheters as Recited in Claim 70

Claim 70 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first a and second catheters reside within a blood vessel of a patient" in combination with "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."

Wijay fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel." Rather, as discussed above, Wijay discloses a balloon 16 in the annular passage 30, which is not located at a distal end of the lumen to prevent blood flow thereinto, as recited in claim 70. The balloon 16 is positioned along a length of the annular passage 30 to seal off the annular passage 30 for distal hemoperfusion. (*See* Wijay, col. 4, ll. 16 - 19; Fig. 1). This positioning of the balloon 16 in the Wijay device allows blood and other fluids to enter the annular passage 30. Furthermore, it is noted that the second sealing balloon 17 of the Wijay device also does not cure the deficiencies of the first balloon 16. Specifically, it is noted that the balloon 17 is not positionable within a distal end of the lumen, as noted in claim 70. Rather, the balloon 17 is situated and inflated in the stenosis. (*See* Wijay, col. 4, ll. 13 - 16). It is therefore noted that the Wijay device is not directed to a catheter that may position a sealing balloon to prevent blood flow into the catheter, as noted in claim 70.

As described above, the recitation of "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, *when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto*" is a structural limitation of the claimed system. It is therefore respectfully submitted that Wijay neither teaches nor suggests "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70 and that claim 70 is allowable. Because

claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Wijay. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Wijay. It is therefore submitted that claim 81 is allowable.

Horzewski also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 70.

As noted above, Horzewski teaches a balloon 82 which is situated along the tubular membrane 77 which contains a plurality of openings 92 and circumferentially placed holes 93. (*See* Horzewski, col. 5, line 65 to col. 6, line 12; Fig. 9). These openings are designed to allow blood to travel to/from the stenosis even during inflation, to avoid even a temporary blockage of blood flow between the catheter and the stenosis. Specifically, Horzewski notes that "[b]lood therefore flows through the dilatation catheter into a region beyond the stenosis so that there is a continued supply of blood to the heart muscle during the period of inflation of the balloon." (*Horzewski*, col. 7, ll. 22 - 28). It is therefore noted that Horzewski does not teach or suggest a catheter that may "seal[s] the distal end of the first lumen to prevent blood flow thereinto," as recited in claim 70. Rather, Horzewski deliberately tries to overcome a situation where blood flow would be blocked by introducing the plurality of openings 92 and circumferentially placed

holes 93 into the design.

It is therefore submitted that Horzewski fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Horzewski. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Horzewski. It is therefore submitted that claim 81 is allowable.

Cannon also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 70.

As noted above, the Cannon device contains a balloon 44 located along a distal end of a guide catheter 12, the balloon 44 being distal to a port 32 and at lease one opening 48 located along the guide catheter 12. (*See* Cannon, col. 3, ll. 7 - 11). Cannon goes on to state that the "guide catheter 12 may have more than one opening to enable fluid communication between the blood vessel BB and the guide lumen 18."(*Cannon*, col. 5, ll. 11 - 14). In light of the above, it is noted that the balloon 44 of the Cannon device is not designated to "seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70. Rather, the balloon 44 is employed to equalize the pressure level inside the catheter, so that a physician may apply a regulated amount of pressure to the blood vessel being infused. (*See*

Cannon, col. 6, ll. 3 - 10). The port 32 and at lease one opening 48 of the Cannon device ensure that, even with the balloon 44 inflated, the injection port is always in fluid communication with the blood vessel.

It is therefore submitted that Cannon fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Cannon. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Cannon. It is therefore submitted that claim 81 is allowable.

4. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and indicate that claims 1 - 27 and 30 - 36 are allowable.

Respectfully submitted,

Date: December 9, 2008

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CLAIMS APPENDIX

1 - 54. (Canceled)

55. (Withdrawn) In combination, a catheter tube for selective flow through a hollow passageway of the catheter tube to or from a patient and a balloon selectively inflated to close and seal the hollow passageway at a distal end of the catheter tube against entry of blood when flow is not occurring through the hollow passageway;

a seal being interposed between the catheter tube and a stem within the hollow passageway at a proximal end of the catheter tube, the stem being selectively displaceable along the hollow passageway through a central opening in the seal, the seal being selectively compressed by a control to clamp against the stem to prevent stem displacement.

56. (Previously Presented) A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient; and

a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto; and

a deflation mechanism for deflating the first balloon to reopen the first lumen to

blood flow thereinto while the distal end of the catheter remains within the blood vessel.

57. (Previously Presented) In combination, a catheter tube comprising a hollow unobstructed passageway for selective liquid flow therethrough to or from a patient and a balloon positionable within the unobstructed passageway and selectively inflated to close, seal and completely occlude all of the hollow passageway at a distal end of the catheter tube against entry of blood when flow is not occurring through the hollow passageway, the balloon comprising an expandable portion of a wall of the catheter tube.

58. (Previously Presented) In combination, ingress and egress catheter tubes for selective flow through a hollow passageway in each catheter tube respectively to and from the patient and a balloon associated with each catheter to accommodating selective inflation of the balloons to generally concurrently close and seal the two hollow passageways at respective distal ends of the ingress and egress catheter tubes against entry of blood from a vessel of the patient when flow is not occurring through the hollow passageways, the balloons being carried near distal ends of spaced inflation/deflation stems extending respectively within the hollow passageways for substantially the full length of the respective catheter tubes;

a seal interposed between each catheter tube and the associated stem within the hollow passageway of said catheter tube at a proximal end of said catheter tube, each stem being selectively displaceable through a central opening with the associated seal;

the seal being selectively compressed by a control to clamp against the associated stem to prevent stem displacement.

59. (Previously Presented) A method of sealing a catheter indwelling within a vessel of a

patient, comprising the acts of:

advancing a first deflated balloon along a first lumen of the catheter to a position at least partially radially within a distal end thereof;

inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen; and

purging the first lumen.

60. (Previously Presented) A method according to claim 59, wherein the first lumen is purged in a proximal-to-distal direction with a suitable liquid under pressure prior to inflating the first balloon.

61. (Previously Presented) A method according to claim 59, wherein the first lumen is purged after inflating the first balloon using a purging liquid under pressure to temporarily deform and unseal the first balloon.

62. (Previously Presented) A method according to claim 59, further comprising:

deflating the first balloon to eliminate the occlusion of the first lumen; and

causing one of ingress and egress flow through the first lumen after the first balloon has been deflated.

63. (Previously Presented) A method according to claim 62, further comprising withdrawing

the first balloon along the first lumen after deflating the first balloon and before causing flow through the first lumen.

64. (Previously Presented) A method of sealing a catheter indwelling within a vessel of a patient comprising the acts of:

terminating flow along a hollow interior passageway of the catheter;

after the terminating act, inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway;

deflating the previously inflated balloon to unseal the hollow interior passageway when flow through the hollow interior passageway of the catheter is desired; and

withdrawing the balloon from the catheter after the deflating act.

65. (Previously Presented) A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

a catheter including a lumen extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient; and

a balloon which, when inflated, physically contacts, and seals the distal end of the

lumen to prevent blood flow thereinto; and

a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

66. (Previously Presented) The system according to Claim 65, wherein the balloon is carried near a distal end of an inflation/deflation stem, the stem extending within the lumen between the proximal and distal ends of the catheter.

67. (Withdrawn) A combination according to Claim 66 wherein the stem carries distance indicia for locating the balloon at the distal end of the catheter tube.

68. (Previously Presented) The system according to Claim 66, wherein a seal is interposed between the catheter and the stem within the lumen at the proximal end of the catheter, the stem being selectively displaceable along the lumen through a central opening in the seal.

69. (Previously Presented) The system according to Claim 65, further comprising a port adjacent the proximal end of the catheter by which a flushing liquid under pressure is selectively displaced proximal-to-distal within the lumen.

70. (Previously Presented) A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein,

when in an operative position, the distal ends of the first a and second catheters reside within a blood vessel of a patient;

first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto; and

a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

71. (Previously Presented) The system according to Claim 70, further comprising a first inflation/deflation stem extending within the lumen of the first catheter and a second inflation/deflation stem extending within the lumen of the second catheter, wherein each of the first and second stems extends for substantially the full length of the first and second catheters, respectively and wherein the first and second balloons are carried near distal ends the first and second stems, respectively.

72. (Previously Presented) The system according to Claim 71, wherein a contiguous seal is interposed between proximal ends of the first and second catheters and the first and second stems, respectively, within the lumen of the respective one of the first and second catheter, each of the first and second stems being selectively displaceable along the lumen of the respective one of the first and second catheters through a central opening in the corresponding seal.

73. (Withdrawn) A combination according to Claim 72 further comprising a pathway along each catheter tube by which fluid under pressure is delivered to the associated balloon to

selectively inflate and deflate the associated balloon.

74. (Previously Presented) The system according to Claim 70, further comprising a port near the proximal end of each catheter by which a flushing liquid under pressure is selectively displaced proximal-to-distal within the corresponding lumen.

75. (Previously Presented) A method according to claim 59, wherein the catheter includes a second lumen, further comprising:

advancing a second deflated balloon along the second lumen to a position at least partially radially within a distal end thereof;

inflating the second balloon to seal the second lumen at the distal end thereof to prevent fluid from entering the distal end of the second lumen; and

prior to inflating the second balloon, purging the second lumen.

76. (Previously Presented) A method according to claim 75, wherein the second lumen is purged in a proximal-to-distal direction with a suitable liquid under pressure prior to inflating the second balloon.

77. (Previously Presented) A method according to claim 75, wherein the second lumen is purged after the second balloon has been inflated using a purging liquid under pressure to temporarily deform and unseal the second balloon.

78. (Previously Presented) A method according to claim 75, further comprising:

deflating the second balloon to eliminate the occlusion of the second lumen; and

causing one of ingress and egress flow through the second lumen after the second balloon has been deflated.

79. (Previously Presented) A method according to claim 78, further comprising withdrawing the second balloon along the second lumen after deflating the second balloon and before causing flow through the second lumen.

80. (Previously Presented) A method of treating a bodily fluid, comprising the steps of:

inserting a distal end of a catheter into a body lumen including the bodily fluid;

establishing fluid communication with the body lumen via a first lumen of the catheter to initiate a first treatment session to treat the bodily fluid;

sealing the first lumen to discontinue fluid communication with the bodily fluid by:

advancing a first deflated balloon along the first lumen to a position at least partially radially within a distal end thereof; and

inflating the first balloon to seal the first lumen at the distal end thereof; and

reestablishing fluid communication with the bodily fluid by deflating the first balloon to initiate a second treatment session.

81. (Previously Presented) The system according to claim 56, further comprising a second sealing balloon positionable within a distal end of the second lumen, so that, when inflated, the second balloon seals the distal end of the second lumen to prevent blood flow thereinto, wherein the deflation mechanism deflates the second balloon to reopen the second lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.